VIA ELECTRONIC SUBMISSION TO:
chronic_care@finance.senate.gov

The Honorable Orrin Hatch
Chairman
Committee on Finance
United States Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate

The Honorable Johnny Isakson
Senator
Committee on Finance
United States Senate

The Honorable Mark Warner
Senator
Committee on Finance
United States Senate

Dear Chairman Hatch, Ranking Member Wyden, Senator Isakson, and Senator Warner:

Omada Health is pleased to submit comments in response to the Bipartisan Chronic Care Working Group Policy Options Document released in late-December, 2015. We commend the Committee for convening this working group and for bringing many of these critical issues to the forefront of the policy discussion.

As stated in the Policy Options Document, the working group *"is considering recommending that Medicare Part B provide payment for evidence-based lifestyle interventions that help people with prediabetes reduce their risk of developing diabetes."* Omada is very pleased to see this policy under consideration. In the comments submitted to the working group in June, 2015, we shared our thoughts on the importance of preventing or delaying type 2 diabetes among people in Medicare to avoid and/or mitigate the human and economic toll of diabetes. Specifically, we recommended the working group support Medicare coverage for the National Diabetes Prevention Program (National DPP), an evidence-based lifestyle intervention, for Medicare beneficiaries with prediabetes.

At Omada Health, we recognize the effect that two key overlapping trends – including a rise in the number of Medicare beneficiaries in the next two decades, and a growing percent of the population at risk for diabetes – stand to have on the Medicare program. We've worked to effectively translate the CDC's National Diabetes Prevention Program (NDPP) into a technology enabled, remotely-delivered Intensive Behavioral Counseling program that has achieved clinical outcomes that meet or exceed those of the average in-person intervention, and published those outcomes in peer-reviewed medical journals. In 2015, our flagship program *Prevent* was one of the very first

among a growing class of digital programs recognized by the CDC as meeting the evidence-based standards of the NDPP. Our most recent data demonstrate that participants in our program maintained clinically meaningful reductions in body weight and blood sugar levels two years after starting the program[1]. In addition to the CDC's recognition of digital diabetes prevention programs, we have been encouraged by recent federal actions supporting the role of digital tools in solving the national diabetes epidemic.

A recent study by the consulting firm Avalere demonstrated that including the NDPP as a reimbursable Medicare benefit could reduce Medicare spending by $1.3 billion in the first decade, with additional savings accelerating in the next 10 years. This amount reflects a combination of an estimated $7.7 billion in new spending on the diabetes prevention program, offset by an estimated $9.1 billion in savings.

Notably, a Center for Medicare and Medicaid Innovation (CMMI) demonstration project, operated by YMCA of the USA, has been running for 3 years with the goal of testing the clinical benefits and budgetary impact of providing coverage for the National DPP to Medicare beneficiaries. Final results will be available in late February, but initial returns show promising results. The project's actuarial analysis has been being fast-tracked as a result, and a variety of policy stakeholders are weighing in with support for coverage.[2]

The demonstration project results, along with Avalere's analysis, provide deep validation of the Working Group's recommendation that Medicare Part B provide payment for evidence-based lifestyle interventions, like the National DPP, that help people with prediabetes reduce their risk of developing diabetes.

Entities Eligible to Deliver Program

With regards to the working group's request for feedback on whether to allow a diabetes prevention program to be delivered by entities that are currently not providers under the Medicare statute, **Omada Health strongly urges the working group to allow such entities, including, but not limited to, non-profit organizations, departments of health**

1 Sepah S.C, Jiang L, Peters AL. Long-Term Efficacy of an Internet-Based Diabetes Prevention Program: 2-Year Study Outcomes. J Med Internet Res 2015;17(4):e92.

2 A December 2015 letter, sent by Senator Al Franken and several of his House and Senate colleagues, to Health and Human Services Secretary Sylvia Burwell, encouraged Secretary Burwell to expand coverage for NDPP to all Medicare beneficiaries, based in part on the results of this highly successful CMMI demonstration.

and federally-qualified health centers, to deliver the National DPP. Currently, the CDC – the established authority on excellence in delivering evidence-based translations of the NDPP - allows for recognition of non-Medicare providers, including non-profit organizations like the Y-USA and for-profit entities like Omada Health. In addition, the Medicare Diabetes Prevention Act includes the following definition for "diabetes prevention program provider" which is inclusive of non-profit organizations, certified diabetes educators, departments of health and federally-qualified health centers:

> *"a diabetes prevention program provider may be, as determined appropriate by the Secretary, a supplier (as defined in subsection (d)), a provider of services (as defined in subsection (u)), a health insurance or services company, a community-based organization, or any other appropriate entity."*

In a recent clinical study conducted by Omada Health, a cohort of approximately 500 beneficiaries in a Medicare Advantage plan administered by Humana achieved clinically meaningful engagement and weight loss outcomes while using *Prevent*, our technology enabled, remotely-delivered Intensive Behavioral Counseling program. With an average age of nearly 70, these participants engaged with the *Prevent* program consistently and with ease. Six months after beginning the program, more than 85 percent of participants remained active - an engagement level among the best-in-class for intensive behavioral counseling (remote or in-person). Most importantly, six months after beginning the program, *Prevent's* Medicare Advantage graduates lost an average of 8.7 percent of their body weight - a level associated with a 71 percent reduction in 3-year risk for developing type 2 diabetes. These results indicate that not only were seniors able and eager to engage with a digital health program, but that they were capable of achieving momentous clinical results. We believe these results have significant implications for CMS, and its ability to have quick and profound impact – through coverage of NDPP and specifically scalable, digital versions of such programs - on the clinical and expense epidemic of type 2 diabetes in US seniors.

Program Requirements

The working group is also considering what additional requirements entities delivering evidence-based lifestyle interventions like the National DPP should be required to meet in order to be recognized as a provider. The CDC's Diabetes Prevention Recognition Program (DPRP) has published set of standards that entities are required to meet in order to be recognized as an eligible provider of the National DPP. The CDC ensures that prevention

program providers are trained and delivering an intervention that is faithful to the one used in the original clinical trial[3] in order to achieve desired outcomes. The DPRP standards support recognition of DPP providers that deliver the program in a face-to-face setting, as well as 'virtual providers' like Omada Health's *Prevent* program, which are delivered remotely using technology to support patient interaction with personal health coaches, evidence-based curriculum, the social accountability and support of patient groups, and more. The convenience of virtual DPP programs serves the needs of seniors who are either too busy, too home-bound, or too financial constrained to attend remote and in-person classes on a weekly basis, and the unprecedented levels of long-term engagement in Omada's *Prevent* program supports this hypothesis. Plus, virtual programs have been shown to have similar weight loss outcomes to in-person programs, as well as the ability to lower average blood sugar levels from the prediabetic range to the normal glycemic range in a treated population.

Omada Health encourages the working group, in its recommendation for coverage of the NDPP, to support the CDC's Diabetes Prevention Recognition Program (DPRP) standards as the guidelines by which DPP providers will qualify for reimbursement for delivery of the NDPP. It should be noted, that in the Medicare Diabetes Prevention Act, the Secretary of Health and Human Services is required to establish criteria for a diabetes prevention program in accordance with the standards under the CDC's National DPP.

Sincerely,

Sean Duffy
CEO and Founder - Omada Health

3 Diabetes Prevention Program Research Group: Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med 346:393-403, 2002.